JAN 2 9 2002

K013959

Summary of Safety and Effectiveness

ASC:180 and ADVIA Centaur Valproic acid Immunoassay

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

3.1 Submitter Information

Contact person:	Kenneth T. Edds, Ph.D.
Address:	Bayer Diagnostics Corporation 511 Benedict Ave. Tarrytown, NY 10591 Phone: 914-524-2446 FAX: 914-524-2500 e-mail: ken.edds.b@bayer.com
Date Summary Prepared:	November 12, 2001

3.2 Device Information

Proprietary Name:	ADVIA Centaur and ACS:180 Valproic Acid Immunoassay
Common Name:	Valproic acid Immunoassay

3.3 Predicate Device Information

Name:	TDx Valproic acid assay
510(k) number:	K904226
Manufacturer:	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064

3.4 Device Description

The ACS and ADVIA Centaur Valproic acid assay is a competitive chemiluminescence immunoassay intended for the quantitative determination of valproic acid in human serum and plasma. Valproic acid in the patient sample, calibrators, standards and controls competes with acridinium ester-labeled valproic acid in the Lite Reagent for a limited amount of monoclonal mouse anti-valproic acid antibody, which is covalently coupled to paramagnetic particles in the Solid Phase. Following incubation, non-reacted acridinium ester-labeled valproic acid and non-reacted valproic acid from the sample is washed from the reaction mixture. The chemiluminescence of the bound, labeled valproic acid is measured in a luminometer. The measured chemiluminescence is inversely proportional to the quantity of valproic acid in the sample.

3.5 Statements of Intended Use - Comparison

- **ACS Valproic acid**

  "For the **quantitative determination of valproic acid** in serum or plasma using the ACS:180 Automated Chemiluminescent Systems. **For In Vitro diagnostic use.**"

- **ADVIA Centaur Valproic acid**

  "**For in vitro diagnostic use** in **the quantitative determination of valproic acid** in serum or plasma using the ADVIA Centaur System."

- **TDx Valproic acid**

  "The TDx/TDxFLx Valproic acid assay is a reagent system for **the quantitative measurement of valproic acid**, an anticonvulsant drug, in serum or plasma. The measurements obtained are used in monitoring levels of valproic acid to ensure appropriate therapy."

3.6 Summary of Technological Characteristics

The ADVIA Centaur and ACS:180 Valproic Acid assay uses a competitive immunoassay format that employs paramagnetic particles and chemiluminescence technology. Both assays use the same reagents, standards and calibrators. In addition the sample size and reagent volumes in the cuvette are the same on both analyzers. Due to analyzer differences, the incubation time differs by approximately 15 seconds. Data from both platforms is used to file for 510(k).

3.7 Method Comparison

Substantial equivalence of the ACS and ADVIA Centaur Valproic acid assay to the predicate device is seen.

These correlation studies demonstrate that the ACS:180 & ADVIA Centaur Valproic acid assay is equivalent to each other as well as the predicate device.

Reference Assay	Test Assay	Slope	Intercept	Correlation Coefficient (r)	N
TDx valproic acid	ADVIA Centaur Valproic acid	0.96	4.03	0.99	250
TDx valproic acid	ACS:180 Valproic acid	0.98	1.37	0.99	250
ACS:180 Valproic acid	ADVIA Centaur Valproic acid	0.97	3.37	0.99	253

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 9 2002

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarytown, NY 10591-5097

Re: k013959
Trade/Device Name: ADVIA Centaur and ACS: 180 Valproic Acid Assay
Regulation Number: 21 CFR 862.3645; 21 CFR 862.3200
Regulation Name: Neuroleptic drugs radioreceptor assay test system; Clinical toxicology calibrator
Regulatory Class: Class II; Class II
Product Code: LEG; DKB
Dated: November 29, 2001
Received: November 30, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name: ADVIA Centaur and ACS:180 Valproic Acid Assay

Indications for Use:

The ACS:180 and ADVIA Centaur Valproic Acid Immunoassays are competitive, chemiluminescence immunoassay for the quantitative determination of valproic acid in human serum and plasma for use on the automated analyzers marketed by Bayer Corporation. Valproic acid (2-propylpentanoic acid) is an anticonvulsant that is used alone or in combination with other anticonvulsant drugs to control seizures. Monitoring of valproic acid ensures that there is adequate drug in the blood stream without being at toxic levels. The ACS:180 and ADVIA Centaur Valproic Acid Immunoassays are used as an aid to monitor patients' valproic acid level.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013959

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) **(Optional Format 1-2-96)**